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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,366	08/22/2001	J. Fernando Bazan	15631-0004801US	1749

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	#12

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,366	Applicant(s) Bazan
	Examiner Prema Mertz	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 6, 2003*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7, 9, 10, and 12-17* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-7, 9, 10, and 12-17* is/are rejected.

7) ☒ Claim(s) *2* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 8, 11 have been canceled previously in Paper No.4 (3/28/02). Claims 5-6, 9-10, 12-15, 17, and amended claims 1-4, 7, 16 (Paper No. 10, 2/6/03), are under consideration.

2. Receipt of applicant's arguments and amendments filed in Paper No. 10 (2/6/03) is acknowledged.

The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 10, 2/6/03:

(i) the rejection of claim 16 under 35 U.S.C. § 112, second paragraph. However, Applicant's argument with respect to claim 16 is rendered moot in light of the new ground of rejection.

3. Applicant's arguments filed in Paper No. 10 (2/6/03), have been fully considered but were persuasive in part. The issues remaining and new issues, are stated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Formal matters

5. Amendments to the claims may only be made as set forth in 37 CFR 1.173(b)(2), as follows:

Any change to the text of a claim (original or new) must be presented as an entire numbered claim. All subject matter being added to an original patent claim must be underlined. All subject matter being deleted from an original patent claim must be placed between brackets. 37 CFR 1.173(b)(2) and (d). Subject matter being added to a new claim requires rewriting (and underlining) of the entire new claim.

In the instant application, the amendments submitted in Paper No. 7 (9/10/02) and Paper No. 10 (2/6/03), have been improperly submitted but were entered. It is requested that Applicants submit a single amendment with all the above mentioned amendments relative to the allowed claims in U.S. Patent pursuant to 37 CFR 1.173(b)(2) and (d).

6. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-7, 9-10, 12-17 are rejected as being based upon a defective declaration under 35 U.S.C. 251. See 37 CFR 1.175.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

Since amendments have been made subsequent to the last oath/declaration, for any error corrected, which is not covered by an oath or declaration i.e., any error corrected after the filing of all declarations currently in the reissue application, applicant must submit a supplemental oath or declaration prior to allowance.

7. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Claim Rejections - 35 USC § 112, first paragraph

Rejection under 35 USC § 112, first paragraph-enablement

8a. Claims 1, 3-7, 9-10, 12-17 are rejected under 35 U.S.C. § 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 2-5 of the previous Office action (Paper No. 8, 10/30/02).

Applicant argues that the claimed DNA sequences are not limited to one that encodes a polypeptide that has the same biological function as IL-B30. Applicant also argue that the polynucleotide is claimed in terms of a defined sequence and not in terms of a functional polypeptide. However, contrary to Applicant's arguments, Applicant's claims include DNA sequences that encode polypeptides that have the same biological function as IL-B30 because in the instant specification (see column 14, lines 55-65), Applicant discloses that the genus of mutant IL-B30 polypeptides include those that share biological activities of the polypeptide with an amino acid sequence set forth in SEQ ID NO:2.

The claimed genus of IL-B30 polypeptides encompasses (1) variants that share activity, however, the specification does not teach how to make a polynucleotide sequence encoding a polypeptide having an amino acid sequence less than SEQ ID NO:2, 4, 5, that would share those activities and (2) variants that do not share IL-B30 activity, however, the specification does not teach how to use these variants that do not share IL-B30 activity. Applicants are not claiming polynucleotide sequences that are "probes" but polynucleotide sequences that encode IL-B30 proteins. The specification only enables polynucleotides encoding IL-B30 proteins of amino acid

sequences set forth in SEQ ID NO:2, 4, or 5 and is not enabled for a polynucleotide encoding a polypeptide having an amino acid sequence anything less than what is disclosed in SEQ ID NO:2, 4 or 5, the claimed polypeptides having specific characteristics (differentially expressed in immune activated cells).

The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The recitation of "at least 17 contiguous amino acids..." in claim 1(b) for example, is not a sufficient structural limitation and broadly encompasses any protein comprising 17 contiguous amino acid sequences recited in the claims. Because of the presence of the term "comprising" in claim 1, the claim encompasses a polynucleotide encoding a polypeptide comprising any 17 contiguous amino acids from 1-175 of SEQ ID NO:4, and therefore the claim encompasses polypeptide embodiments encompassing any other 158 amino acid sequences or more in addition to these 17 contiguous amino acids. The number of polypeptide embodiments in this case are over 5×10^{207}. Similarly the recitation of "at least 40 contiguous amino acids..." in claim 1(a) encompasses over 4×10^{168} embodiments.

Furthermore, the instant specification does not provide the guidance needed to use these polynucleotides as claimed. Even if Applicants recited a functional limitation for the IL-B30 polypeptide in the instant claims, Applicants have not taught how to make the instant polynucleotides encoding polypeptides with the stretch of 40, 17 or 30 contiguous amino acids as recited in claim 1. The instant specification does not teach which polynucleotides encoding polypeptides would

predictably be associated with that function. There is no guidance in the specification for how to make and use polynucleotides encoding proteins having the amino acid sequences anything less than that disclosed in SEQ ID NO:2, 4 or 5.

Applicants arguments on page 5 that the standard is that routine experimentation is required to identify the numerous embodiments is a position that has been routinely dismissed by the courts, as shown by the CAFC decision in Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a polynucleotide encoding a polypeptide comprising at least 17 contiguous amino acids of SEQ ID NO:4. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the three disclosed naturally-occurring proteins, which are required for functional and structural integrity of those proteins. It is this additional characterization of the three disclosed proteins that is required in order to obtain the structural data needed to permit one to produce the claimed polynucleotide encoding a protein which meets the structural requirements of the instant claims that constitutes undue experimentation.

With respect to the term "conservative substitutions" recited in claim 16, Applicants argue that a skilled artisan would recognize that the claim is limited to substitutions made in a particular polypeptide to a discreet set of amino acids with similar characteristics. However, contrary to Applicants arguments, claim 16 is overly broad since no guidance is provided as to which of the myriad of polynucleotide encoding protein species encompassed by the claim will retain the desired biological properties of an IL-B30 polypeptide and the claims broadly encompass a significant number

of inoperative species. Applicants argue that the teachings of the present application, especially when taken together with the knowledge of one of ordinary skill in the pertinent art, provide an enabling disclosure for present claim 16. However, contrary to Applicants arguments, the specification (column 14, lines 18-44) merely outlines residues which are considered conservative. This is not adequate guidance as to the nature of the polynucleotide analogues or variants that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Therefore Applicants have not presented enablement commensurate in scope with the claims.

Applicant argues on page 6 of the response that the claims in this invention are analogous to those discussed in the "Training Materials for Examining Patent Applications with Respect to 35 USC 112, First Paragraph- Enablement in Chemical/Biological Applications," Example N. However, contrary to Applicant's arguments, the instant claims are properly subject to a 35 USC 112, first paragraph rejection as in Example N. Claim 1 in the Example recites the entire DNA sequence encoding a protein, algernin, and nucleotide fragments thereof at least 15 nucleotides in length. Similarly, claim 2 in the Example recites the entire DNA sequence encoding algernin. However, claim 3 which claims "an isolated DNA that encodes a 50 amino acid peptide that has algernin activity." Any protein of any amino acid sequence but this activity would be encompassed by the scope of the claim. The specification failed to identify those amino acid residues essential for biological activity and those that are expendable or substitutable. It would involve undue experimentation to rationally design a DNA encoding a functional protein having anything other than the disclosed amino acid

sequence. The instant claims, in contrast to Example N claims 1-2, are not comprising full-length polynucleotides encoding a protein with a specific activity but are rather drawn to molecules comprising fragments with no activity.

Rejection under 35 USC § 112, first paragraph-written description

8b. Claims 1, 3-7, 9-10, 12-17 are rejected under 35 U.S.C. § 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 5-6 of the previous Office action (Paper No. 8, 10/30/02).

Applicant argues that the genus of the claimed invention is sufficiently described in the specification to convey to one of ordinary skill in the art that Applicant had possession of the claimed genus of polynucleotide sequences encoding IL-B30. Furthermore, Applicant argues that the specification clearly describes the claimed sequences as a portion of the full-length sequence encoding IL-B30 isolated from human,mouse, and pig, i.e. SEQ ID Nos: 2, 4, and 5 respectively and that these complete amino acid sequences would convey to one of skill in the art that Applicant was in possession of the encoding DNA sequence. However, contrary to Applicant's arguments, claims 1, 3-7, 9-10,12-13, 14, 16-17 encompass a genus of polypeptides that comprise only portions of the full-length sequence encoding IL-B30 isolated from human mouse, and pig, i.e. SEQ ID Nos: 2, 4, and 5 respectively as well as polynucleotide variants encoding IL-B30 proteins having one or more amino acid deletions, insertions and/or additions made to SEQ ID NO: 2, 4 and 5. The specification and claims do not indicate what are the distinguishing attributes shared by the members of the genus for

which the common portion is responsible for functional activity. The specification and claims (except for claim 16) do not place any limit on the number of amino acids that may be added to the portions since the claims are not limited to the full-length SEQ ID NO:2, 4, and 5. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted.

Applicant argues that while the genus encompasses a large number of embodiments, it is not unpredictably variant and that variance is limited to that tolerated by the genetic variance in coding sequence for a particular amino acid in the disclosed sequence. However, contrary to Applicant's arguments, although the specification states that these types of changes are routinely done in the art (see column 14, lines 18-44), the specification and claims do not provide a written description as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural and functional attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, polynucleotides encoding SEQ ID NOs: 2, 4, 5, alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus.

Applicant argues that the three full-length species are representative of the claimed genus. However, contrary to Applicants arguments, even though a genetic code table would correlate the human, mouse and pig amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the members of a genus comprising only small portions of the full-length sequence. Thus, at the time the application was filed, the amino acid sequences of other mammalian IL-B30 proteins i.e. rodent, canine, feline, etc., other than human, mouse and pig, were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

Rejection under 35 USC § 112, first paragraph-new matter

8c. Claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

i) Claim 3, line 2, recites "... at least 65°C" which language is new matter in the claim, since the instant specification fails to disclose a temperature of 65°C. The specification fails to provide proper support for this language in the claims for the following reason:

Column 22, lines 26-30, discloses that the present invention encompasses stringent temperature conditions usually including temperatures in excess of about 30°C, usually in excess of about 37°C, typically in excess of about 55°C, preferably in excess of about 70°C. The specification does not disclose the specific temperature of 65°C as recited in the claim. The range of temperatures

as disclosed in the specification are not equivalent to the specific temperature recited in claim 3. This rejection can only be obviated by reciting the specific range of temperatures for which there is support in the instant specification.

(ii) Claim 3, lines 1-2, recites "...residues 155-164 of SEQ ID NO:2" which language is new matter in the claim, since the instant specification fails to disclose this range of residues in SEQ ID NO:2. The specification fails to provide proper support for this language in the claims for the following reason:

Column 12, lines 55-64, discloses that the present invention encompasses a human soluble IL-B30 having amino acid sequence corresponding to a soluble polypeptide of SEQ ID NO:2. Furthermore, column 20, lines 39-43, discloses that biologically active proteins or fragments of SEQ ID NO:2 are contemplated by the instant invention. However, the instant specification does not disclose amino acid residues 155-164 of SEQ ID NO:2 as recited in the claim 3. The biologically active proteins or fragments of SEQ ID NO:2 as disclosed in the specification are not reflective of the specific amino acid range recited in claim 3. This rejection can be obviated by reciting a specific range of amino acids for which there is support in the specification.

(iii) Claim 4, line 3, recites "...contiguous nucleotides are from nucleotides 580-670 of SEQ ID NO:3" which language is new matter in the claim, since the instant specification fails to disclose this stretch of contiguous nucleotides 580-670 of SEQ ID NO:3. The specification fails to provide proper support for this language in the claims for the following reason:

Column 21, lines 35-42, discloses that the present invention encompasses contiguous nucleic acid segments of at least 17, 22, 35, 41, 47, 55, or 60 or more nucleotides, eg. 67, 73, 81, 89, 95, etc. However, the instant specification does not disclose that the contiguous nucleotides are from nucleotides 580-670 of SEQ ID NO:3 as recited in the claim 4. The "at least 67 contiguous nucleotides... of SEQ ID NO:3" as disclosed in the specification is not reflective of the specific nucleotide range recited in claim 4. This rejection can be obviated by reciting a specific range of nucleotides for which there is support in the specification.

New Rejection under 35 USC § 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 14, 16-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, lines 1-2, is vague and indefinite because it recites "...which encodes amino residues..." rather than "...which encodes amino acid residues...".

Claim 4 is improper because it recites "...polynucleotide encoding a polypeptide comprising at least 67 contiguous nucleotides...". However, a polynucleotide comprises nucleotides, a polypeptide comprises amino acids. This rejection can be obviated by amending the claim to recite that the polynucleotide comprises "at least 67 contiguous nucleotides".

Claim 16 is broader than claim 2 but is improperly dependent on claim 2 instead of being dependent on claim 1. Alternatively, claim 2 could depend from claim 16 which in turn should be dependent on claim 1. Appropriate correction is required.

Claim 17, sub-part(d) recites "encodes an antigenic polypeptide having at least 12 amino acid residues", which limitation is vague and indefinite because by dependency from claim 1, the smallest possible encoded polypeptide is 17 amino acids, so the limitation fails to limit the size of the encoded polypeptide and it is unclear what this limitation is further limiting. It is unclear if Applicants are claiming the sequence of claims 1 and 3 further including an epitope. Furthermore, since all polypeptides are antigenic it is unclear what specifically the term "antigenic" defines.

Claim 14 is rejected as vague and indefinite insofar as it depends on claim 3 for its limitations.

Conclusion

No claim is allowable.

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

An isolated or recombinant polynucleotide encoding a polypeptide of amino acid sequence set forth in SEQ ID NO:2, 4, or 5 is allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
May 22, 2003